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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,417	05/04/2001	Ib Mendel-Hartvig	1614-0248P	7800

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,417	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 February 2005 has been entered.
2. Claim 4 has been cancelled.
3. Claims 1-3 and 5-11 are pending.
4. The text of those US Codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112

5. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing with respect to the description of the housing. It is unclear whether the housing or a portion thereof is made of a transparent or translucent material.

Claim Rejections - 35 USC § 102

6. Claims 1-3 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al (US 5,602,040) for reasons of record in the previous office which are reiterated herein below.

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier. The device contains a labeled specific binding reagent for an analyte. The labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte, which unlabeled reagent, is permanently immobilized in a detection zone on the carrier material. (Column 2, lines 3-20). May teaches an embodiment where the device contains a control zone containing an anhydrous reagent that when moistened, produces a color change or color formation. The control zone is located downstream from the detection zone. (Column 5, lines 8-27) May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (column 3, lines 22-32). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (column 9, lines 19-30). Quantitative

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measurement may be done visually by eye or by instrument. May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (column 7, lines 15-20). Specifically, May teaches laminating the porous carrier to a transparent moisture-impermeable plastic material and that the transparent strip is in contact with the upper inner surface of the casing (column 14, lines 33-41). May also teaches an absorbent sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (column 5, line 58 through column 6, line 6). May teaches that the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which the binding reaction can occur. Controls over these parameters can be achieved by the incorporation of viscosity modifiers such as sugars and modified celluloses to slow down the reagent migration (column 7, lines 30-39). May also teaches that the casing or housing is provided with means that enable the various zones to be observed from outside the housing (column 3, line 60 through column 4, line 8). May specifically disclosed that the spatial separation between the zones and the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which the necessary specific binding can occur (column 7, lines 30-39).

Claim Rejections - 35 USC § 103

7. Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over May et al (US 5,602,040).

May differs from the instant invention in failing to specifically teach that the time indicator substance is applied to wicking member or to a support, which is in turn applied to the wicking member. However, May specifically teaches that the absorbent sink (i.e. wicking member) is either chromatography paper applied to the porous solid phase, or a length of porous solid phase material that extends beyond the detection zone (column 6, lines 1-6). May also teaches that the control zone (i.e. time indicator) is located downstream from the detection zone (column 5, lines 8-26), therefore, it can clearly be seen that the time indicator taught by May is located directly on the wicking member, or as an alternative, it is located on the wicking member and the wicking member is disposed on the test strip.

8. Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Gattiglia (US 6,655,315 B1).

See the discussion of May above. May teaches an embodiment where a moisture-absorbant material such as silica gel is included in the device to maintain the strip in the dry state. See column 12, lines 40-43. However, May differ from the instant invention in failing to teach that the silica gel may be used as an assay end-point indicator.

Gattiglia discloses novel silica gel for use as indicator labels in chemical products. Gattiglia teaches that silica gel, with copper chloride as active principles in combination with a mixture of hygroscopic salts, changes color when wet and are advantageously used as a moisture indicator. See columns 1 and 2. Gattiglia teaches that the indicator labels may be soaked or sprayed onto a paper support.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention is made to use the indicator labels-soaked support taught by Gattiglia in the device of May because both May and Gattiglia teaches that is necessary to have means that can maintain and indicate the moisture conditions inside chemical packaging. Furthermore, the use of the indicator labels taught by Gattiglia in the device of May would have provide the advantage of a dual function, i.e. one that can maintain the device in a dry condition and also serve to notify the user that liquid applied to the device has migrated to the end-point assay indicator.

Response to Arguments

9. Applicant's arguments filed 03 February 2005 have been fully considered but they are not persuasive.

Applicant argues that May does not anticipate the instant invention because May fails to teach that the indicator is arranged in contact with the wicking member at a variable position downstream of a flow matrix or a detection zone. Applicant also

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argues that May does not teach that any portion of the housing should be formed with a transparent or translucent portion.

These arguments have been fully considered but are not persuasive. May teaches the same device of the instant invention including the same means for indicating the end of the assay, i.e. a control zone comprising a dye. As indicated in the previous action, the term variable means changeable (i.e. capable of being changed or moved); however, since the claims are directed to a *product* and not a *method of making the product*, and since the claims do not specifically state that the indicator would be changed or moved in the device, the indicator, as claimed is seen to be an end-point indicator placed in a specific location to indicate the end of an assay. The feature that enables the indicator to be arranged in different locations on the wicking member appears to be accomplished during manufacture of the device, thus, it is not a limitation of the device itself. Furthermore, because May teaches that spatial separation between the various zones, and the flow rate characteristics of the porous carrier material (i.e. wicking membrane), can be selected to allow adequate reaction times during which the necessary specific binding can occur, and to allow the labeled reagent in the first zone to migrate through the carrier (column 7, lines 30-39), May clearly recognizes and teaches variable positioning of the reagents including the dye indicator.

The argument that May does not teach or suggest a housing having any transparent or translucent portion as required in the device of claim 1 is not persuasive.

Applicant asserts that the transparent plastic strip visible through the apertures taught by May is intended to be a seal against ingress of moisture or sample into the casing, and does not teach or suggest the instant device including a housing having a transparent or translucent portion thereof which allows variable positioning of an indicator on a wicking member. It is noted that the device of claim 1 is recited as having a housing enclosing the flow matrix and wicking material where the indicator is included on an inner side of the housing at a transparent or translucent portion thereof. This does not necessary means that the housing has a transparent or translucent portion. Only that the indicator is located in a position that is translucent or transparent, as such, May anticipates this feature. Furthermore, even if the housing has a portion that is transparent or translucent, it is alternatively obvious over the teaching of May because May teaches that the housing can be optional and the nitrocellulose sheet carrying the various zones can be sandwiched between two supporting sheets of plastic (column 7, lines 22-23), and teaches that the plastic supports can be transparent (column 12, lines 27-31).

The argument that May fail to teach varying the position of the control zone or any element therein particularly at a location where the housing is provided with a translucent or transparent portion is not persuasive.

May teaches that spatial separation between the various zones, and the flow rate characteristics of the porous carrier material (i.e. wicking membrane), can be selected to allow adequate reaction times during which the necessary specific binding can occur,

and to allow the labeled reagent in the first zone to migrate through the carrier (column 7, lines 30-39). Therefore, May clearly recognizes and teaches variable positioning of the reagents including the dye indicator. Furthermore, May teaches that the window or aperture locations are lined with transparent plastic to allow observation of the results, therefore, May clearly teaches that the housing is "provided" with a transparent or translucent portion.

The argument that Gattiglia does not make up for the alleged deficiency of May is not persuasive. May teaches moisture absorbant including silica gel and Gattiglia teaches that silica gels are well known for use as moisture indicators, therefore, it would have been obvious to use the indicator labels-soaked support taught by Gattiglia in the device of May because both May and Gattiglia teaches that is necessary to have means that can maintain and indicate the moisture conditions inside chemical packaging. Furthermore, the use of the indicator labels taught by Gattiglia in the device of May would have provide the advantage of a dual function, i.e. one that can maintain the device in a dry condition and also serve to notify the user that liquid applied to the device has migrated to the end-point assay indicator.

Conclusion


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571).

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272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

4/11/05